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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) NAGACO.055A	
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Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>54,198</u>		 Russell M. Jeide Typed or printed name <u>951-781-9231</u> Telephone number <u>August 4, 2005</u> Date	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____			
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PRE-APPEAL BRIEF

Applicant : Cohen, et al.
App. No : 09/989,684
Filed : November 20, 2001
For : APPARATUS AND METHODS FOR
SEPARATING AGGLUTINANTS
AND DISPERSE PARTICLES
Examiner : Samuel P. Siefke
Art Unit : 1743

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August 4, 2005

(Date)

Russell M. Jeldo
Russell M. Jeldo, Reg. No. 34,198

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Pre-Appeal Brief is being filed in response to the Office Action dated May 4, 2005. This Brief does not include claim amendments and is being filed with a Notice of Appeal.

Remarks

Claims 9, 12, 15-31, 77, 78, and 91-94 are currently pending in this application. These claims are listed in the amendment dated February 4, 2005. As outlined below, Applicant respectfully asserts that there is clear error in the claim rejections included in the May 4, 2005 Office Action. In view of the comments below, Applicant respectfully requests reconsideration of the pending claims and issuance of a Notice of Allowance by this Pre-Appeal Panel.

Discussion of the Pending Claims

The claims of the present application are generally directed towards systems and methods of quantifying the presence of certain particles in a sample. The pending claims each refer to an optical disc having a separation structure configured to separate particle agglutinants from disperse particles. As those of skill in the art will recognize, particles of interest in a biological compound may be agglutinated by the addition of one or more proper reagents having an affinity for the particles of interests, where the remaining particles are not agglutinated by addition of the reagent. As recited in the pending claims, the particle agglutinants may then be separated from the remaining disperse particles. As explained in paragraph 9 of the present application:

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A biological sample material is dispensed into the entry chamber. An assay reagent including particles bound with at least one type of bioactive agent is dispensed into the entry chamber. The biological sample material is mixed with the assay reagent. The biological sample material is allowed to react with the assay reagent to thereby facilitate formation of an agglutinant. The optical disc is rotated so that non-agglutinated particles escape from the entry chamber through the separation zone structure. Where the agglutinated particles remain, the disc is made to allow an interrogating light beam to be reflected from or transmitted past the particles to allow detection, imaging, and/or counting of the particles.

Claims 9, 77, 78, and 91 are the currently pending independent claims. Each of these claims is rejected in the May 4, 2005 Office Action under 35 U.S.C. §102(e) as being anticipated by Virtanen (U.S. Patent No. 6,030,581). Each of the above-listed independent claims are believed to be allowable for reciting at least one of two features, specifically (1) separating particle agglutinants from disperse particles and (2) quantifying an amount of separated disperse particles. The claims are believed to also be allowable for their own unique features.

Discussion of Virtanen

Virtanen describes, in general:

[An] optical disk, adapted to be read by an optical reader, comprising a first sector having substantially self-contained assay means for localizing an analyte suspected of being in a sample to at least one, predetermined location in the first sector and a second sector containing control means for conducting the assay and analyte location information, with respect to one or more analytes suspected of being in a sample, accessible to the reader, wherein the presence or absence of the analyte at said location is determinable by the reader using the control means and the location information. *Virtanen*, Abstract.

In *Virtanen*, an "analyte binds to a predetermined location on the disk if it is present in the sample, and the presence of the analyte is detected by the reader from information that identifies the particular analyte with the location at which it is bound." *Id.* at col. 5, ll. 44-48. Thus, *Virtanen* appears to determine if a particular analyte is present in a sample by detecting, using various means, whether any analyte binds to respective locations of the optical disk, where the location information indicates at which respective location each of the analytes of interest will bind, if present in the sample.

Virtanen Does Not Teach or Suggest Quantifying an Amount of Separated Particle Agglutinants and/or Disperse Particles

Claim 77 recites, in pertinent part:

An optical disc for separating disperse particles from particle agglutinants, comprising: a plurality of tracks disposed on an outer periphery of the optical disc ... wherein a quantity of disperse particles may be determined by using the light detector to count a number of the plurality of tracks that are covered by the disperse particles.

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Thus, the apparatus of Claim 77 determines an approximate quantity of disperse particles contained in a sample by counting a number of tracks on the outer periphery of the optical disc that are at least partially covered by disperse particles that have passed through the separation structure.

Applicant respectfully submits that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. See M.P.E.P. § 2131. The portion of Virtanen cited by the Examiner as teaching this quantification apparatus recites: "[t]he analyte binds to a predetermined location on the disk if it is present in the sample, and the presence of the analyte is detected by the reader from information that identifies the particular analyte with the location at which it is bound." While Virtanen may detect the presence of a particular analyte based upon its location on the optical disc, Virtanen does not teach or suggest any quantification of disperse particles. Furthermore, Virtanen does not teach or suggest quantifying disperse particles using a detector "to count a number of the plurality of tracks that are covered by the disperse particles."

Independent Claims 9 and 78 each include quantification systems or methods similar to those recited in Claim 77. For example, Claim 9 recites, "[a]n optical disc comprising a tracking groove positioned at least partly beneath the entry chamber and proximate the separation structure, wherein particle agglutinants in the entry chamber can be quantified by determining an amount of the tracking groove that is at least partly covered by particle agglutinants," and Claim 78 recites that "a quantity of particle agglutinates may be determined by using the light detector to count a number of the plurality of tracks that are covered by the particle agglutinates." Thus, Applicant respectfully asserts that Virtanen fails to teach or suggest at least the above-quoted elements of Claims 9 and 78 for the same reasons as discussed above with respect to Claim 77. Reconsideration of Claims 9, 77 and 78, and their pending dependent claims, is respectfully requested.

Virtanen Does Not Teach or Suggest Separating Particle Agglutinants From Disperse Particles

Claim 77 recites, in pertinent part:

An optical disc for separating disperse particles from particle agglutinants, comprising ... a separation structure comprising solid components spaced apart to form gaps, the gaps being large enough to allow disperse particles to change position relative to the center of the disc by passing through the separation structure, the gaps being too small to allow particle agglutinants to pass through the separation structure.

Thus, the separation structure recited in Claim 77 separates particle agglutinants from disperse particles through the use of solid components having gaps specifically sized to be large enough to allow the disperse particles to pass through, but narrow enough to stop the particle agglutinants from passing through.

The portion of Virtanen cited by the Examiner as teaching the separation structure recites:

Filters may be used to remove large particles, such as cells, dust, etc. from the soluble sample. Accordingly, filters are most preferably included as part of the sample inlet compartment. Filters may be formed from porous plastic, glass, cross-linked cotton or cellulose, etc. These materials may be in the shape of rods or similar shapes

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depending on the particular use to which they are being put. Plastics, such as Teflon, may be used as films. *Virtanen*, Col. 7, ll. 35-43.

Applicant respectfully submits that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. See M.P.E.P. § 2131. Applicant submits that *Virtanen* does not expressly teach or suggest separation structures including solid components with gaps therebetween, "the gaps being large enough to allow disperse particles to change position relative to the center of the disc by passing through the separation structure, the gaps being too small to allow particle agglutinants to pass through the separation structure" *Virtanen* does not disclose, or even mention, separation of disperse particles and particle agglutinants. *Virtanen* states that "[f]ilters may be used to remove large particles, such as cells, dust, etc. from the soluble sample," but this clearly does not anticipate filtering of particle agglutinants from disperse particles and, going one step further, does not anticipate the spacing of components of a separation structure as a function of particle agglutinant size.

Independent Claims 9, 78, and 91 each include one or more separation structures similar to the separation structure recited in Claim 77. For example, Claim 9 recites:

An optical disc comprising ... a separation structure positioned between the entry chamber and the collection zone, the separation structure comprising a plurality of structures that define gaps therebetween, the distance between the gaps being less than or equal to the width of the particle agglutinants, the separation structure being configured to separate particle agglutinants from the disperse particles when the specimen is urged toward the separation structure by centrifugal force created when the optical disc is rotated;

Claim 78 recites:

An optical disc for separating disperse particles from particle agglutinants, comprising ... a separation structure having solid components spaced apart to form gaps, the gaps being sized so that particle agglutinates are retained in the entry chamber while disperse particles are allowed to pass through the separation structure into the collection zone when the optical disc is rotated;

and Claim 91 recites:

An optical disc comprising ... a first separation structure positioned between the entry chamber and the collection zone, the separation structure comprising a plurality of structures defining at least a first gap therebetween, a width of the at least a first gap being greater than a width of at least a portion of the particle agglutinants, and a second separation structure positioned between the first separation structure and the collection zone, the second separation structure comprising a plurality of structures defining at least a second gap therebetween, a width of the at least a second gap being less than or equal to a width of substantially all of the particle agglutinants.

In view of the above, Applicant asserts that *Virtanen* does not anticipate any of the pending independent claims. Reconsideration of Claims 9, 77, 78, 91, and their pending dependent claims is respectfully requested.

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Discussion of Provisional Double Patenting Rejection

On page 2 of the May 4, 2005 Office Action, the Examiner indicates that each of the pending claims is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-57 of co-pending U.S. Patent Application No. 09/997,895 ("the '895 Application"). Applicant respectfully traverses this provisional rejection and, in view of the below comments, respectfully requests removal of this rejection.

While certain claims of the '895 Application do recite a "separation chamber," the '895 Application claims fails to recite filtering of particle agglutinants from disperse particles. Furthermore, the '895 Application claims fail to recite the use of spaced component in a separation structure, wherein gaps between the components are sized so that particle agglutinants are stopped at the separation structure while smaller disperse particles pass through the separation structure. Applicant respectfully asserts that the '895 Application fails to teach or suggest at least this separating feature, as described above. Accordingly, removal of this rejection is respectfully requested.

Summary

In view of the above, Applicant respectfully requests reconsideration of Claims 9, 77, 78, 91 and their pending dependent claims. Issuance of a Notice of Allowance by the Pre-Appeal Panel is respectfully requested.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 4, 2005

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